REMARKS

Claims 1-37, 47, 64-70 and 88-92 are active in this application.

The Examiner's courtesy for meeting with Applicant's representatives and the named inventors is appreciated. During this meeting it was explained why the delivery systems of the cited Kitajima and Schobel patents would not inherently achieve a tensile strength of at least 10,000 psi as set forth in Claim 1 of the present application. In particular, the methodology employed by Kitajima and Schobel utilize solvents and as a result would generally result in tensile strengths much lower than that which is claimed due to the inevitable remaining solvent or solvent residue and the morphology of the encapsulated materials that would result from Kitajima and Schobel's processes.

During the meeting samples were presented that demonstrated the effect solvent has on tensile strength. Those samples were: a pure sample of polyvinyl acetate, a sample of polyvinyl acetate with some solvent, and a delivery system that had been produced according to what is described in the application in which the active was aspartame (a sweetener). The purpose of these samples was not for quantitative purposes but simply for qualitative assessment of how different tensile strengths affect the physical characteristics of polymers. The pure polymer having a very high tensile strength (e.g., greater than 10,000 psi) was hard, difficult to break (if at all), and if broken was very brittle. However, when the polymer included some solvent, like that in the Kitajima and Schobel patents, the sample was quite pliable and easy to break/bend indicative of a tensile strength of about less than 5,000 psi.

Therefore, it was stressed that neither Kitajima nor Schobel describe compositions which inevitably result each and every time with compositions having the tensile strength defined in the claims.

Further discussion on these points in the context of each of the cited patents is provided below.

The Examiner has maintained the rejections under §102(b) based on Kitajima (U.S. Patent No. 3,691,090) or Schobel (U.S. Patent No. 4,824,681). The issue that underlies each of these three rejections is the same, i.e., each allegedly teaches encapsulated products but describe or suggest nothing with the respect to the tensile strength of that encapsulated products. Nonetheless, the Examiner has taken the position that tensile strength would be inherent because the cited art teach the same encapsulating material and the same active. However, that the same starting materials are used to prepare the "capsules" is relevant, but not a determinative, inquiry. Indeed, how the active is encapsulated and the properties of the end product are the relevant issues to assess and because the rejections do not discuss why it is believed that the cited end products (the "capsules") would necessarily have the tensile strength defined in the claims, the Office has not met its burden showing that the cited materials necessarily, each and every time meet what is claimed in the present application.

Nonetheless, Applicants explain below why the "capsules" of Kitajima and Schobel would not necessarily have a tensile strength as is defined in the claims.

In the way of background it should be appreciated that the tensile strength of a composition will depend on the composition itself, the morphology of the solid material distributed in the composition and solvent residue. Indeed, even minor amounts of solvent, e.g., about 0.5%, have a dramatic lowering effect on the tensile strength of the encapsulation. As explained during the aforementioned meeting, the methodology employed by Kitajima and Schobel utilize solvents and as a result would generally result in tensile strengths much lower than that which is claimed.

The Kitajima rejection

Kitajima describes a process for the preparation of capsules containing a core material, where the core material is dispersed in a solution of an organic solvent and an encapsulating material. (see col. 1, lines 40-45). The suspension (core material and encapsulating material/solvent) is then dispersed in an aqueous salt solution and then the organic solvent is removed (*Id.*). Kitajima emphasizes the necessity of the solvent in the process because it is the selection of solvent that is asserted as the invention:

> The principle of the method of this invention is in the utilization of not only an organic solvent having a low polarity but also an organic solvent having a high polarity which is miscible with water and causes phase separation when it is mixed with an aqueous inorganic salt solution and in the utilization of drops of a solution of a polymer in an organic solvent suspended in an aqueous inorganic salt solution without being mixed therewith maintain their shape during evaporating the organic solvent through an aqueous phase when the system is maintained at a slightly reduced pressure or at elevated temperature. (col. 1, line 63 to col. 2, line 7)

In col. 3, Kitajima provides further description of the encapsulation methodology:

> . . . The core material is dispersed in the polymer solution and the dispersion is suspended in a concentrated aqueous solution of an inorganic salt forming droplets. . . (lines 44-47)
>
> The organic solvent is evaporated away by only stirring the system, but it is advantageous to stir the system at such a reduced pressure and/or increased temperature that the droplets are not broken. . . (lines 49-52)

This is also how each of Kitajima's Examples make the capsules (see col. 4-8), e.g., in Example 1:

> In a solution of 0.5 g of polycarbonate in 20 g of dioxane was dispersed 2.1 g carbon black and the resulting dispersion was dispersed in a concentrated aqueous solution of 90 g of

> ammonium sulfate in 150 ml of water at 20° C with stirring the system vigorously. Thereafter, by heating the system to 50 °C for 2 hours, the solvent was evaporated away and polycarbonate capsules containing carbon black having a uniform diameter of about 2 mm were formed, which were washed with water, recovered and dried.

This Kitajima process results in capsules with core shell type morphology, see e.g., col. 3, lines 59-65 (See also FIG. 1 and FIG. 2 of Kitajima):

> When the system is stirred in such condition, the organic solvent in the suspended droplet is evaporated off through the aqueous phase to deposit the polymer enwrapping the droplets of core material, whereby a substantially spherical capsule is obtained. By this procedure, capsules in spherical form having diameters of from 20 microns to 5 millimeters can be formed.

Such a thin layer of encapsulating material surrounding the active core would not necessarily have a tensile strength anywhere close to 10,000 psi (as in the claims). Further, under the conditions Kitajima describes for removing the solvent after dispersion (see above), no matter how hard one tries there will be a remaining solvent residue in the end product capsules. Because of the core shell morphology and solvent residue, the end product capsules will not, each and every time, have the minimum tensile strength as claimed.

Withdrawal of the rejection based on Kitajima is requested.

The Schobel rejection

Schobel does describe an encapsulated sweetener where the coating material comprises a hydrophobic polymer and a hydrophobic plasticizer and the polymer can be polyvinyl acetate phthalate (see col. 3, lines 37-42 and col. 7, lines 14-26). Again, Applicants arguments pertaining to Schobel were not that Schobel doesn't describe starting materials that would fall within the definitions of the materials defined in claim 1 but rather that the end product or the delivery system itself that Schobel makes having these starting materials would not inherently have a tensile strength as is claimed.

So how does Schobel make the encapsulated sweetener? Schobel describes in the paragraph bridging col. 8-9 that the encapsulation is prepared by spray drying, coacervation, or a fluidized bed coating process:

> The present method of preparing the sweetening composition comprises encapsulating the sweetening agent or sweetening component with the coating materials within the parameters set forth above. Sweetening agent or sweetening component may be encapsulated by a variety of coating techniques, including **spray drying, coacervation**, and the like. Preferably, the sweetening agent or sweetening component is encapsulated by a method that operates in a similar fashion to **fluidized bed coating processes**, in which particles of sweetening agent or sweetening component are suspended in an apparatus that creates a strong upward air current or stream in which the particles move. (emphasis added)

Each of these procedures utilizes a solvent to prepare an encapsulation. In the instance of spray drying, the polymeric material is dissolved in a solvent and sprayed onto the sweetener. The coacervation technique involves mixing solvents containing the sweetener and the polymer and in the fluidized bed, much like the spray drying technique, the solvent dissolved polymer is passed through a specialized apparatus to effect coating (see also col. 9, lines 1-16 of Schobel).

This is what Schobel describes in the Examples found in col. 10-12. In Example 1, starting at line 66 of col. 10, Schobel describes the coating method:

> Add plasticizer to **aqueous emulsion** of hydrophobic polymer and mix for about 20 minutes until plasticizer is uniformly dispersed in the emulsion. Add sweetener and water to the mixture and continue mixing for about 10 minutes or until uniform. Charge a Strea-1 (Aeromatic) coating machine with the sweetener granules and apply coating. Both granulations IA and IB above were coated using the following parameters. (emphasis added)

The morphohology and residual solvent in the spray encapsulated material, the coacervation process, and the fluidized bed coating process described by Schobel will not, each and every time, have the minimum tensile strength as claimed. That is, as explained in the context of the Kitajima rejection, (1) the coating of polymer that surrounds the sweetener would not have sufficient thickness to impart any appreciable amount of tensile strength to the level that is claimed; and (2) the residual solvent that would remain would preclude those compositions from inherently achieving a 10,000 psi tensile strength.

Withdrawal of the rejection based on Schobel is requested.

There are also several provisional obviousness-type double patenting rejections in view of co-pending cases. Those co-pending applications are 11/134,356; 11/134,365; 11/134,367; 11/134,370; 11/134,371; 11/134,480; and 11/135,153. A Terminal Disclaimer is attached here to address these provisional rejections.

Favorable reconsideration and allowance of all pending claims is requested.

Should the Examiner have any questions or wish to discuss any aspect of this application, he is invited to contact the undersigned.

Respectfully submitted,

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